Haematological and infectious complications associated with the treatment of patients with congenital cardiac disease: consensus definitions from the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease

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Abstract: A complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome. A complication does not necessarily represent a breech in the standard of care that constitutes medical negligence or medical malpractice. An operative or procedural complication is any complication, regardless of cause, occurring (1) within 30 days after surgery or intervention in or out of the hospital, or (2) after 30 days during the same hospitalization subsequent to the operation or intervention. Operative and procedural complications include both intraoperative/intraprocedural complications and postoperative/postprocedural complications in this time interval. The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease has set forth a comprehensive list of complications associated with the treatment of patients with congenital cardiac disease, related to cardiac, pulmonary, renal, haematological, infectious, neurological, gastrointestinal, and endocrinal systems, as well as those related to the management of anaesthesia and perfusion, and the transplantation of thoracic organs. The objective of this manuscript is to examine the definitions of operative morbidity as they relate specifically to the haematological system and to infectious complications. These specific definitions and terms will be used to track morbidity associated with surgical and transcatheter interventions and other forms of therapy in a common language across many separate databases. The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease has prepared and defined a near-exhaustive list of haematological and infectious complications. Within each subgroup, complications are presented in alphabetical order. Clinicians caring for patients with congenital cardiac disease will be able to use this list for databases, quality improvement initiatives, reporting of complications, and comparing strategies for treatment

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Original Article

Haematological and infectious complications associated with the treatment of patients with congenital cardiac disease: consensus definitions from the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease

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Abstract A complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome. A complication does not necessarily represent a breech in the standard of care that constitutes medical negligence or medical malpractice. An operative or procedural complication is any complication, regardless of cause, occurring (1) within 30 days after surgery or intervention in or out of the hospital, or (2) after 30 days during the same hospitalization subsequent to the operation or intervention. Operative and procedural complications include both intraoperative/intraprocedural complications and postoperative/postprocedural complications in this time interval.

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The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease has prepared and defined a near-exhaustive list of haematological and infectious complications. Within each subgroup, complications are presented in alphabetical order. Clinicians caring for patients with congenital cardiac disease will be able to use this list for databases, quality improvement initiatives, reporting of complications, and comparing strategies for treatment.

Keywords: Congenital heart disease; quality improvement; patient safety; outcomes; registry; operative morbidity; paediatric; surgery; congenital abnormalities; cardiac surgical procedures; heart; sepsis; mediastinitis; infection; haematology

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Through the work of a variety of individuals, societies, and organizations, the reporting and analyzing of outcomes related to the treatments of patients with congenitally malformed hearts has increased substantially.[1–4] These ongoing efforts have yielded a fundamental expectation of providing performance metrics that will be utilized by patients, providers, and payers. The value of these metrics relies upon a quantifiable standard for quality of care. Efforts to date have concentrated on global measures of outcomes, such as mortality,[3] length of stay,[5] or utilization of resources. While these measures are important, it is recognized that need exists to develop better measurement parameters of performance, as well as accurate and universally accepted measures of morbidity associated with surgery for congenital cardiac disease. Prior to defining quality of care, a universal nomenclature must be developed that defines the complications associated with the treatment of patients with congenital cardiac disease. It is necessary to develop the tools to allow for the careful analysis of not only the success associated with surgical performance, but also of complications. These complications must be assessed and documented in a reproducible and measurable fashion.

A working group representing the MultiSocietal Database Committee for Pediatric and Congenital Heart Disease was convened to approach analysis of organ based complications. This group undertook the evaluation of complications associated with the treatment of patients with congenital cardiac disease, related to cardiac, pulmonary, renal, haematological, infectious, neurological, gastrointestinal, and endocrinal systems, as well as those related to the management of anaesthesia and perfusion, and the transplantation of thoracic organs. The Societies and organizations represented in the MultiSocietal Database Committee for Pediatric and Congenital Heart Disease are presented in the Introduction to this Supplement. The objective of this manuscript is to examine the definitions of operative complications as they relate specifically to the haematologic system and to infectious complications. Specific definitions and terms, adjudicated by consensus, could serve as a common language, which could be used to track rates of morbidity associated with surgical intervention across databases.

Historical background

Previous attempts at describing and monitoring haematological and infectious complications have been limited to descriptive presentations by individual centres or by individual countries.[6–10] To date, however, the descriptions have not been standardized, neither with regards to nomenclature, nor to their definition or analysis. This shortcoming has led to wide variability in the haematological complication rates associated with cardiac surgery, with published rates ranging from 0.03% to 3.5%, a more than ten-fold difference. This variation in reported complication rate can be explained in part by the fact that some groups include only haemorrhagic complications as haematological complications, others have concentrated on thromboembolic complications, and yet others have included the complications associated with any use of blood components. This discrepancy has led to incomplete representation of risk and benefit associated with treatment, thus resulting in confusing and conflicting data.

Consensus definitions

In Part 4 of this Supplement, within each organ system, complications are presented and defined in alphabetical order. The process for creating this list of complications began in 1998 with initiation of the International Congenital Heart Surgery Nomenclature and Database Project of The Society of Thoracic Surgeons and The European Association for Cardiothoracic Surgery.[11] In April of 2000, common database standards for congenital heart surgery were published and incorporated into the databases of The Society of Thoracic Surgeons and The European Association for Cardiothoracic Surgery. This effort was followed in 2005 by the formation of MultiSocietal Database Committee for Pediatric and Congenital Heart Disease and its Risk Factor and Complications Subcommittee, with the task of reaching clear, specific and universally acceptable definitions of risk factors and complications.

The Congenital Heart Surgery Databases of The Society of Thoracic Surgeons and The European Association for Cardiothoracic Surgery have used a common Complications Short List since 2000. A need existed to agree upon a comprehensive Complications Long List. Starting with the Complications List of The Society of Thoracic Surgeons and The European Association for Cardiothoracic Surgery, a draft of a more complete Complications Long List was created, with further breakdown within this list as to which complications are specific for the intra-operative time frame. This work was initially presented at a meeting of The Society of Thoracic Surgeons Congenital Database Taskforce in 2006.

The next steps of the group were to create a Complications Long List acceptable to all of the members of MultiSocietal Database Committee for Pediatric and Congenital Heart Disease. This Complications Long List would then become part of the International Pediatric and Congenital Cardiac Code (IPCCC). This Complications Long List would be mapped to a more manageable

Complications Short Lists that can be used in multi-institutional databases. The project was organized by dividing the Complications Long List by organ systems. Subcommittees were created for each organ system, with representatives included from each of the societies and groups in the MultiSocietal Database Committee for Pediatric and Congenital Heart Disease. The authors of this manuscript represent the subgroup that was tasked with defining haematological and infectious complications.

Each subcommittee evaluated the Long Lists and Short Lists of the various member Societies and proposed definitions for all of the terms in each list. Particular emphasis was placed on the following two Long Lists and Short Lists:

- The International Congenital Heart Surgery Nomenclature and Database Project[11] of The Society of Thoracic Surgeons and The European Association for Cardiothoracic Surgery
- The European Paediatric Cardiac Code of The Association for European Pediatric Cardiology.[12]

Experts in a particular organ system were consulted for assistance in definition development at the discretion of the individual subcommittees. These definitions were then circulated to all participants. Finally, a summit was held to discuss and finalize all definitions. These adjudicated definitions will be used in the multiple databases of various member Societies that compose the MultiSocietal Database Committee for Pediatric and Congenital Heart Disease and the terminology will be incorporated into the International Pediatric and Congenital Cardiac Code [www.ipccc.net]. The original working list of hematologic and infectious complications is found in Table 1 of this manuscript. The terms in Table 1 served as the starting point and were fused with complementary terms from several other lists including The European Paediatric Cardiac Code.[12] Table 2 lists the terms in the final list of haematologic and infectious complications. These terms in the final list are all also listed in Part 4 of this Supplement with their official definitions.

Infections involving vascular lines, or "line infections", and infections involving wounds, or "wound infections" are discussed in detail in the manuscript in this Supplement titled "Integument, Vascular, Vascular-Line(s), and Wound Complications associated with Congenital Cardiac Surgery: Consensus Definitions from the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease". In Part 4 of this Supplement, these infectious complications are then listed and defined under the system headings of "Vascular-Line(s)" and "Wound" respectively.

Table 1. The Initial List of Haematologic and Infectious Complications.

Haematologic complications

1. Anticoagulant complication
2. Anticoagulant complication, Secondary to intraoperative heparin
3. Other
4. Protamine reaction
5. Reaction to antifibrinolytic drug
6. Reaction to aprotinin
7. Reaction to blood products
8. Reaction to blood products, Reaction to packed red blood cells
9. Reaction to blood products, Reaction to plasma
10. Reaction to blood products, Reaction to platelets

Infectious complications

1. Endocarditis
2. Endocarditis, Bacterial
3. Endocarditis, Fungal
4. Infection, Multiple
5. Mediastinitis
6. Other
7. Pneumonia
8. Sepsis
9. Sepsis Staph epi, In blood
10. Sepsis, Enterobacter, In blood
11. Sepsis, Multi-system Organ Failure
12. Sepsis, Pseudomonas, In blood
13. Sepsis, Septic shock
14. Sepsis, Staph aureus – MRSA, In blood
15. Sepsis, Staph aureus – non-MRSA, In blood
16. Sepsis, Staph aureus, In blood
17. Sepsis, Yeast, In blood
18. UTI
19. UTI, Bacterial
20. UTI, Bacterial, Pseudomonas
21. UTI, Yeast

Infections involving the lungs, such as pneumonia, are discussed in detail in the manuscript in this Supplement titled "Pulmonary Complications". In Part 4 of this Supplement, these infectious pulmonary complications are then listed and defined under the system heading of "Pulmonary".

Also in Part 4 of this Supplement, Endocarditis is listed and defined under the system heading of "Cardiac".

Controversies

Overall, working group consensus was achieved for most of the list of the haematological and infectious complications. The major source of controversy centred on defining the time course for each complication. This was felt to be important since some agents, such as protamine, will elicit a near-immediate reaction,

Table 2. The Final List of Haematologic and Infectious Complications.

Precise definitions for these complications are given in Part 4 of the Supplement

Haematologic complications

1. Anaphylactic or anaphylactoid reaction to antifibrinolytic drug
2. Anaphylactic or anaphylactoid reaction to antifibrinolytic drug, Reaction to tranexamic acid
3. Anaphylactic or anaphylactoid reaction to antifibrinolytic drug, Reaction to aminocaproic acid
4. Anaphylactic or anaphylactoid reaction to antifibrinolytic drug, Reaction to aprotinin
5. Anticoagulant complication
6. Anticoagulant complication, Difficulty in achieving adequate anticoagulation
7. Anticoagulant complication, Hemorrhagic
8. Anticoagulant complication, Heparin Induced Thrombocytopenia (HIT)
9. Anticoagulant complication, Prothrombotic
10. Anticoagulant complication, Secondary to intraoperative/intraprocedural heparin
11. Cold agglutinin reaction
12. Hematologic complication
13. Protamine reaction
14. Protamine reaction, Biochemically confirmed
15. Protamine reaction, Clinically suspected
16. Prothrombotic and/or hemorrhagic reaction to antifibrinolytic drug
17. Prothrombotic and/or hemorrhagic reaction to antifibrinolytic drug, Reaction to tranexamic acid
18. Prothrombotic and/or hemorrhagic reaction to antifibrinolytic drug, Reaction to aminocaproic acid
19. Prothrombotic and/or hemorrhagic reaction to antifibrinolytic drug, Reaction to aprotinin
20. Reaction to blood products
21. Reaction to blood products, Post-transplant graft versus host disease
22. Reaction to blood products, Reaction to cryoprecipitate
23. Reaction to blood products, Reaction to packed red blood cells
24. Reaction to blood products, Reaction to plasma
25. Reaction to blood products, Reaction to platelets
26. Reaction to blood products-modifier
27. Reaction to blood products-modifier, ABO mismatch transfused
28. Reaction to blood products-modifier, Administration of wrong blood product
29. Reaction to blood products-modifier, Error from improperly identifying patient
30. Reaction to blood products-modifier, Major
31. Reaction to blood products-modifier, Minor
32. Sickle cell crisis

Infectious complications

Please note the following:

- Endocarditis is listed and defined under the system heading of "Cardiac".
- Infections involving the lungs, such as pneumonia, are listed and defined under the system heading of "Pulmonary".
- Infections involving vascular lines, or "line infections", and infections involving wounds, or "wound infections" are listed and defined under the system headings of "Vascular-Line(s)" and "Wound" respectively.

1. Infection
2. Infection, Multiple
3. Infection-modifier for causative organism
4. Infection-modifier for causative organism, Bacterial
5. Infection-modifier for causative organism, Bacterial, Enterobacter
6. Infection-modifier for causative organism, Bacterial, Enterococcus
7. Infection-modifier for causative organism, Bacterial, Enterococcus (Vancomycin-resistant enterococci [VRE])
8. Infection-modifier for causative organism, Bacterial, Etiology unknown
9. Infection-modifier for causative organism, Bacterial, Etiology unspecified
10. Infection-modifier for causative organism, Bacterial, Gonococcal
11. Infection-modifier for causative organism, Bacterial, Haemophilus
12. Infection-modifier for causative organism, Bacterial, Klebsiella

Table 2. *Continued*

13. Infection-modifier for causative organism, Bacterial, Meningococcal
14. Infection-modifier for causative organism, Bacterial, Pneumococcal
15. Infection-modifier for causative organism, Bacterial, Pseudomonas
16. Infection-modifier for causative organism, Bacterial, Pseudomonas aeruginosa
17. Infection-modifier for causative organism, Bacterial, Spirochetal
18. Infection-modifier for causative organism, Bacterial, Staphylococcal
19. Infection-modifier for causative organism, Bacterial, Staphylococcal, Staphylococcus aureus
20. Infection-modifier for causative organism, Bacterial, Staphylococcal, Staphylococcus aureus, Methicillin-resistant Staphylococcus aureus (MRSA) negative
21. Infection-modifier for causative organism, Bacterial, Staphylococcal, Staphylococcus aureus, Methicillin-resistant Staphylococcus aureus (MRSA) positive
22. Infection-modifier for causative organism, Bacterial, Staphylococcal, Staphylococcus epidermidis
23. Infection-modifier for causative organism, Bacterial, Streptococcal
24. Infection-modifier for causative organism, Bacterial, Syphilitic
25. Infection-modifier for causative organism, Bacterial, Tuberculous
26. Infection-modifier for causative organism, Bacterial, Typhoid
27. Infection-modifier for causative organism, Chlamydial
28. Infection-modifier for causative organism, Etiology unknown
29. Infection-modifier for causative organism, Etiology unspecified
30. Infection-modifier for causative organism, Fungal
31. Infection-modifier for causative organism, Fungal, Aspergillosis
32. Infection-modifier for causative organism, Fungal, Candidal
33. Infection-modifier for causative organism, Fungal, Yeast
34. Infection-modifier for causative organism, Non-bacterial infection
35. Infection-modifier for causative organism, Parasitic
36. Infection-modifier for causative organism, Protozoal (not Chagas')
37. Infection-modifier for causative organism, Rickettsial
38. Infection-modifier for causative organism, Toxoplasmosis
39. Infection-modifier for causative organism, Trypanosomal (Chagas' disease)
40. Infection-modifier for causative organism, Viral
41. Infection-modifier for causative organism, Viral, Adenovirus
42. Infection-modifier for causative organism, Viral, Coxsackie virus
43. Infection-modifier for causative organism, Viral, Cytomegalovirus (CMV)
44. Infection-modifier for causative organism, Viral, Echovirus
45. Infection-modifier for causative organism, Viral, Epstein-Barr virus (EBV)
46. Infection-modifier for causative organism, Viral, HIV
47. Infection-modifier for causative organism, Viral, Influenza virus
48. Infection-modifier for causative organism, Viral, Mumps virus
49. Infection-modifier for causative organism, Viral, Rubella
50. Infectious complication
51. Sepsis
52. Sepsis, Multi-system Organ Failure
53. Sepsis, Septic shock
54. Sepsis, Urosepsis
55. Sepsis, With documented bacteremia
56. Sepsis, With documented bacteremia, With Enterobacter in blood
57. Sepsis, With documented bacteremia, With Pseudomonas in blood
58. Sepsis, With documented bacteremia, With Staphylococcus aureus – MRSA (Methicillin Resistant Staphylococcus Aureus) in blood
59. Sepsis, With documented bacteremia, With Staphylococcus aureus – non-MRSA (non-Methicillin Resistant Staphylococcus Aureus) in blood
60. Sepsis, With documented bacteremia, With Staphylococcus aureus in blood
61. Sepsis, With documented bacteremia, With Staphylococcus epidermidis in blood
62. Sepsis, With documented fungemia
63. Sepsis, With documented fungemia, With yeast in blood
64. Sepsis, With documented viremia

Table 2. *Continued*

65. Sepsis, With primary blood stream infection (BSI) = hospital acquired blood stream infection (BSI)
66. Sepsis, With primary blood stream infection (BSI) = hospital acquired blood stream infection (BSI), In a patient with a central venous catheter
67. Sepsis, With primary blood stream infection (BSI) = hospital acquired blood stream infection (BSI), In a patient with an arterial catheter
68. Urinary tract infection (UTI)
69. Urinary tract infection (UTI), Bacterial
70. Urinary tract infection (UTI), Bacterial, Pseudomonas
71. Urinary tract infection (UTI), Yeast

whereas others, such as warfarin or aspirin, may not become manifest until a much later time. There was also considerable discussion regarding the infectious complications of sepsis, septic shock, and the systemic inflammatory response syndrome (SIRS). Finally, the timeliness of the popular terms "ventilator acquired pneumonia", commonly referred to as "VAP", and "blood stream infection", commonly termed "BSI", deserve special attention.

It was agreed that the time course of operative and procedural complications, for both the haematological and infectious systems, would be confined to the period of data collection that begins at "Operating Room Entry Date and Time", as defined in Part 4 of this Supplement and as previously published,[5] and ends when the following criteria have been met:

- 30 days have passed since the original operation or procedure
- the patient has been discharge from the hospital as defined in Part 4 of this Supplement and as previously published.[5]

In other words, an operative or procedural complication is any complication, regardless of cause, occurring (1) within 30 days after surgery or intervention in or out of the hospital, or (2) after 30 days during the same hospitalization subsequent to the operation or intervention. Operative and procedural complications include both intraoperative/intraprocedural complications and postoperative/postprocedural complications in this time interval.

These rules specifically pertain to the diagnosis of Heparin Induced Thrombocytopenia (HIT), in which antibody formation usually occurs within 5–10 days postoperatively. Similarly, specific infectious complications are also tracked within this "operative and procedural" time window. For example, the following definition is provided for "Urinary tract infection (UTI)":

> "A urinary tract infection is an infection of the urinary tract, as defined by positive urine culture or white blood cells (WBCs) present on urinalysis. A urinary tract infection that will be counted as an operative or procedural complication must occur prior to hospital discharge or after hospital discharge but within 30 days of the procedure. (An operative or procedural complication is any complication, regardless of cause, occurring (1) within 30 days after surgery or intervention in or out of the hospital, or (2) after 30 days during the same hospitalization subsequent to the operation or intervention. Operative and procedural complications include both intraoperative/intraprocedural complications and postoperative/postprocedural complications in this time interval.)"

The definition of sepsis was discussed and debated extensively:

> "Sepsis is defined as "evidence of serious infection accompanied by a deleterious systemic response". In the time period of the first 48 postoperative or postprocedural hours, the diagnosis of sepsis requires the presence of a Systemic Inflammatory Response Syndrome (SIRS) resulting from a proven infection (such as bacteremia, fungemia or urinary tract infection). In the time period after the first 48 postoperative or postprocedural hours, sepsis may be diagnosed by the presence of a SIRS resulting from suspected or proven infection. During the first 48 hours, a SIRS may result from the stress associated with surgery and/or cardiopulmonary bypass. Thus, the clinical criteria for sepsis during this time period should be more stringent. A systemic inflammatory response syndrome (SIRS) is present when at least two of the following criteria are present: hypo- or hyperthermia (>38.5 or <36.0), tachycardia or bradycardia, tachypnea, leukocytosis or leukopenia, and thrombocytopenia."

Pneumonia and ventilator acquired pneumonia are discussed in detail in the manuscript in this Supplement titled in the "Pulmonary Complications". Because of the timeliness of the topic of ventilator acquired pneumonia, we will address this issue in this manuscript as well.

No "gold-standard" definition exists for the diagnosis of "ventilator acquired pneumonia", commonly referred to as "VAP". The criteria used to make the diagnosis are controversial. Below, we present the two best published consensus statements for current diagnosis and treatment of ventilator acquired pneumonia.

The first ventilator acquired pneumonia consensus statement guides clinicians and is a product of the American Thoracic Society and the Infectious Disease Association of the America.[13] In brief, ventilator acquired pneumonia diagnostic criteria are applied using a combination of "clinical" and "quantitative" strategies to guide therapy, based on cultures of the lower respiratory tract. These criteria include the occurrence of new and persistent radiographic infiltrates (at least 72 hours) in conjunction with two of three clinical criteria (fever, leukocytosis, purulent secretions) and positive cultures using a threshold greater than 10,000 colony forming units per millilitre (if the patient is on antibiotics longer than 24 hours, a threshold of greater than 1000 colony forming units per millilitre is used). As an invasive approach, bronchoscopic sampling is preferred, but not required, in keeping with the consensus protocol. However, bronchoscopic sampling may be difficult in children.

The second ventilator acquired pneumonia consensus statement guides investigators and is a product of the International Sepsis Forum.[14] Taking into account that final microbiological (culture) data only become available after-the-fact, ventilator acquired pneumonia is defined post-hoc for reporting purposes as falling into one of three categories:

- Microbiologically confirmed or definite: clinically present with abnormal chest radiograph and the isolation of a likely pulmonary pathogen, or the isolation of a likely/possible pulmonary pathogen in high concentration from a quantitative lower respiratory tract sample, or positive serology,
- Probable: clinically present with abnormal chest radiograph but without microbiological or serological confirmation, or
- Possible: abnormal chest radiograph of uncertain cause, with low or moderate clinical suspicion of pneumonia, but with microbiological or serologic criteria of definite or probable pneumonia.[14]

The advantage of this second definition of ventilator acquired pneumonia is that it accurately captures the uncertainty of the diagnosis "in the real world", allowing one to separate out those cases that are culture positive from those cases that have no cultures available or are culture-negative. This stratification improves the predicative models of ventilator acquired pneumonia that we generate, as those models can incorporate and account for variance in attending practice and the clinical certainty (or uncertainty) of the diagnosis of ventilator acquired pneumonia.

Infections of intravascular lines, or "Line infections" are discussed in detail in the manuscript in this Supplement titled "Integument, Vascular, Vascular-Line(s), and Wound Complications associated with Congenital Cardiac Surgery: Consensus Definitions from the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease". Because of the timeliness of the topic of blood stream infections, a brief comment is made in our manuscript as well. Definitions from the Centers for Disease Control and Prevention of the United States of America were used for primary blood stream infections in patients with central venous or arterial catheters.[15] A "primary blood stream infection" may also be considered a "hospital-acquired blood stream infection" and is defined as an infection that began 48 hours or more after hospital admission and was due to pathogenic microorganisms in the blood that were not present or incubating before hospital admission.

Interaction with the cardiac system

Severe infection can cause haemodynamic instability and shock. The following definition is proposed for shock:

> "Shock is defined as 'a state of inadequate tissue perfusion'. A modern definition according to Simeone states that shock is a 'clinical condition characterized by signs and symptoms which arise when the cardiac output is insufficient to fill the arterial tree with blood under sufficient pressure to provide organs and tissues with adequate blood flow.' A historic definition according to Blalock in 1940 is that 'Shock is a peripheral circulatory failure, resulting from a discrepancy in the size of the vascular bed and the volume of the intravascular fluid'."

Septic shock is "a state of inadequate tissue perfusion caused by sepsis". Septic shock is therefore defined as a condition which meets the criteria of the previously listed definitions of both sepsis and shock.

Conclusion

Effective monitoring practices of peri-operative morbidity are dependant upon standardized definitions of the complications themselves. The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease has set forth a comprehensive list of complications associated with the treatment of patients with congenital cardiac disease, related to cardiac, pulmonary, renal, haematological, infectious, neurological, gastrointestinal, and endocrinal systems, as well as those related to the management of anaesthesia and perfusion, and the transplantation of thoracic organs. The objective of this manuscript is to examine the definitions of operative morbidity as they relate

specifically to the haematological system and to infectious complications. These specific definitions and terms will be used to track morbidity associated with surgical and transcatheter interventions and other forms of therapy in a common language across many separate databases.

The areas of haematological and infectious complications are important to the field of congenital cardiac surgery, specifically due to the current emphasis on limiting utilization of blood products and rates of nosocomial infections.[14] Infectious complications are a leading cause of morbidity and mortality after cardiac surgical interventions. Additionally, forthcoming "pay-for-performance" initiatives will potentially limit renumeration to healthcare providers based on the incidence of postoperative infectious complications. The definitions of these complications will, therefore, take on potentially greater significance over time. Haematological complications associated with either a pro- or anti-coagulated state lead to significant morbidity and mortality in our population as well.[16] Analysis of the data on these important post-operative morbidities across databases and centres requires the common nomenclature developed by the consensus of this working group.

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